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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,421	04/09/2004	Peter Ospyka	32469-303686	1219

42074 7590 01/24/2008
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EXAMINER

BERTRAM, ERIC D

ART UNIT	PAPER NUMBER
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3766

NOTIFICATION DATE	DELIVERY MODE
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01/24/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

e-OfficeActionBSc@faegre.com

Office Action Summary

Application No.

10/821,421

Applicant(s)

OSPYKA, PETER

Examiner

Eric D. Bertram

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,19,21-31 and 33-65 is/are pending in the application.
- 4a) Of the above claim(s) 23,26-30 and 51-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,19,21,22,24,25,31 and 33-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/14/07.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- ☐ Notice of Informal Patent Application
- ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Response to Arguments

2. Applicant's arguments filed 10/31/2007 have been fully considered but they are not persuasive. Initially, the applicant argues that the obviousness-type double patenting (ODP) rejections are improper because the copending applications do not qualify as prior art over the current application. This is irrelevant. MPEP § 804 explains that as long as two copending applications that were filed by the same inventive entity, a common inventor or a common assignee, ODP is appropriate and required until one or more of the applications are ready for issue. As applicant knows, 35 USC 101 dictates that a person is entitled to only one patent on an invention, regardless of when the applications were originally filed. Since the ODP is not the only remaining rejection in the current application, the ODP is still considered proper.

3. The applicant further argues that the anchor 122 of Grandjean is not "configured to advance through myocardial tissue in a first orientation and to anchor against an epicardial surface in a second orientation." The Examiner respectfully disagrees. As

stated in the previous Office Action, Peters, US 4,341,226, incorporated by reference into Grandjean, describes that the anchor 122 expands from a straightened strand to an expanded coil when deployed in the operating condition, and when deployed in this position holds (i.e., anchors) the lead in place (see abstract). While it is true that external forces can be applied which would move the anchor, it does not mean that the helix 122 does not act like an anchor without external force applied while implanted. Similarly, an anchor of a boat is configured to hold the boat in place in the water; however, the anchor can be moved by external forces being applied to it. The helix 122 is configured to anchor the apparatus against an epicardial surface if that is where the helix is contacting upon implantation.

4. Furthermore, the applicant has amended the claims to recite that the tension element 120 has a "proximal end and a distal end attached to the anchor." Therefore, based on the applicant's amendment, the "proximal end" of the tension element can be considered the entire length of the element extending from the anchor 122 to connector 102, while the "distal end" of the tension element can be considered the entire length of the element extending from the anchor to the needle 118. Therefore, since the distal end of the lead 100, electrode portion 114, is not connected to the tension element, it allows for some slideable movement along the "proximal end" (as defined above) of the tension element both towards and away from the anchor during implantation.

Furthermore, the proximal end of the lead 100 is coupled to the tension element (Col. 3, lines 32-34).

5. The 35 USC 102(b) and 103(a) rejections of the claims are still considered proper.

Information Disclosure Statement

6. The information disclosure statement (IDS) submitted on 9/14/07 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 18, 19, 21, 22, 24, 25, 31 and 33-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. In claim 18, the second section recites "a tension element having a proximal end and a distal end attached to the anchor." It is unclear whether both the proximal end and the distal end are attached to the anchor, or if only the distal end is attached to the anchor. For examination purposes, it is assumed that the claim only requires that the distal end be attached to the anchor. Since claims 19, 21, 22, 24, 25, 31 and 33-42 depend from claim 18, they are rendered indefinite by their association.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 18, 19, 21, 22, 24, 25 and 31-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 19 and 25 of copending Application No. 10/971,577. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application contain all of the limitations of the current independent claims in addition to many others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 18, 19, 21, 22, 24, 25 and 31-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21, 23 and 24 of copending Application No. 10/971,549. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application contain all of the limitations of the current independent claims

in addition to many others. Furthermore, a method for using the claimed apparatus would be obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 18, 19, 21, 22, 24, 25 and 31-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/972,298. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the copending application contain all of the limitations of the current independent claims in addition to many others. Furthermore, a method for using the claimed apparatus would be obvious to one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 18, 22, 32, 33, 35, 36, 43, 44, 46, 47 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Grandjean et al. (US 5,009,229, hereinafter Grandjean). Grandjean discloses an apparatus capable of being inserted into and stimulating muscle tissue, of which the myocardium of the heart would be included (see

abstract). The apparatus has an anchor 122 for abutting a surface of a muscle, as well as a tension element 120 attached to the anchor (see figures 2, 3 and 6, Col. 3, lines 44-48). The tension element extends from the proximal end of the lead and completely through the pole 114 of electrode 100, which forms an inner guide channel due to its coil (See figure 4 and Col. 3, lines 32-36 and 58-62). Furthermore, the tension element has a "proximal end" that is considered to be the entire length of the element extending from the anchor 122 to connector 102, while the "distal end" of the tension element can be considered the entire length of the element extending from the anchor to the needle 118. Therefore, since the distal end of the lead 100, electrode portion 114, is not connected to the tension element, it allows for some slideable movement along the "proximal end" (as defined above) of the tension element both towards and away from the anchor during implantation. Furthermore, the proximal end of the lead 100 is coupled to the tension element (Col. 3, lines 32-34).

16. Since the tension element is not attached to the electrode, the electrode is inherently allowed to slide over the tension element.

17. Regarding claim 22, the anchor 122 expands from a straightened strand to an expanded coil when deployed in the operating condition, as described in Peters, US 4,341,226, incorporated by reference into Grandjean (Col. 3, lines 45-48).

18. Regarding claims 33, 35 and 46, the tension element is "attachable to" the electrode by pulling the tension element through one of the coils of the electrode, which would then act as a fastening element (see figure 4).

19. Regarding claims 36 and 47, as shown in figure 6, the electrode 114 acts as a stop since it is not permitted to move forward once it makes contact with the muscle.

20. Regarding claim 44, tool 118 is detachably coupled to the anchor (see Peters, US 4,341,226, incorporated by reference into Grandjean).

21. The applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. Claims 38 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandjean in view of Official Notice. Grandjean, as described above, discloses the applicant's basic invention with the exception of the electrode including an anode

spaced apart from a cathode. However, the use of unipolar and bipolar electrodes and pacing is notoriously old and well known in the art as being interchangeable configurations for stimulating muscle tissue. One of ordinary skill in the art would have found it obvious to modify the pole to include both an anode and a cathode to allow for bipolar pacing, especially since this allows for charge balancing, which results in less pain felt by the patient.

25. Claims 39, 40 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grandjean in view of Wesbey et al. (US 3,244,174, hereinafter Wesbey).

Grandjean, as described above, discloses the applicant's basic invention with the exception of having two electrodes branching from a common supply lead for stimulating the heart. Attention is directed to the secondary reference of Wesbey, which discloses a system for implanting multiple conductors in a heart by inserting two conductors 24 extending from a common supply lead into the myocardium of the heart, as shown in figure 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Grandjean by utilizing two leads extending from a common supply as taught by Wesbey in order to stimulate two locations of a muscle at the same time.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday from 8:30-7 EST.

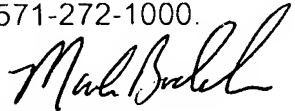
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766


Mark Bockelman
Primary Examiner
Art Unit 3766

EDB